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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,009	12/04/2001	Bob van Gemen	5189US	7686

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EXAMINER
GUNTER, DAVID R

ART UNIT	PAPER NUMBER
1634	14

DATE MAILED: 10/31/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/006,009	Applicant(s) VAN GEMEN ET AL.	
	Examiner David R. Gunter	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 30-35, drawn to a method of determining therapeutic activity and/or toxicity of a candidate compound, classified in class 436, subclass 94.

II. Claim 15, drawn to a method of determining the stage of a disease, classified in class 436, subclass 94.

III. Claims 16, 26-29, 39, and 41-46, drawn to a method of determining therapeutic activity, classified in class 436, subclass 94.

IV. Claims 17-25, drawn to a method of determining therapeutic activity, classified in class 436, subclass 94.

V. Claim 40, drawn to a medicament or other agent selectable or obtainable by the method of Group I, classified in class 514, subclass 1.

VI-LI. Claims 36-38, drawn to a kit comprising at least one primer or probe, classified in class 536, subclass 24.3, each group defined by a distinct sequence defined by SEQ ID NOS: 1-46 in claim 38.

1. Groups I-IV are independent and distinct. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group I recites a method of determining therapeutic activity and/or toxicity of a candidate compound comprising the steps of obtaining a sample from an organism and determining the ratio of a first nucleic acid and/or gene product and a second nucleic acid and/or gene product.

The claims of group II recite a different effect (determining the stage of a disease) and also recite different modes of operation including (1) determining that an organism suffers from or is at risk or suffering from a disease, and (2) determining how the calculated ratio relates to and is indicative of the particular stage of that disease.

The claims of group III recite the effect of determining therapeutic activity, toxic activity, and/or possible side-effects of a candidate compound. The method of group III comprises a different mode of operation than the methods of groups I or II, including the identification of a malfunctioning cellular organism (claim 16), determining the selective activity of the candidate compound (claim 26), and providing an essentially unrelated second organism with the candidate compound (claim 27).

The claims of group IV recite the effect of determining therapeutic activity and/or possible side-effect of a medicament. The method of group IV comprises different modes of operation than the methods of groups I-III, including determining the ratio of gene expression prior to the introduction of the medicament (claim 25), identifying the side-effects of the medicament and further identifying an organism free from said side-effects, and introducing the medicament to an organism free from side-effects (claim 20).

Each of the groups outlined above recite a unique effect and modes of operation which are specific to each group. A literature search for the method steps of any one of the above groups would not be coextensive with a search for all of the above groups, and therefore a search of all of the above groups represents a significant search burden. Because these inventions are independent and distinct for the reasons given above and have acquired a separate status in the

art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

2. Groups I-IV are related to group V as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the agent identified by the method of groups I-IV may be any one of a broad range of chemical compounds including proteins, DNA, and RNA. These compounds each possess unique chemical structures and physical properties, and so constitute materially different products. In addition, medicaments and other bio-active agents can be identified using a plurality of functional assays other than the assay of Group I-IV.

3. Groups VI-LI are each drawn to a patentably distinct sequence comprising a different SEQ ID NO. Applicant is required under 35 U.S.C. 121 to elect **no more than 1 disclosed sequence representing 1** SEQ ID NOs even though this requirement is traversed.

The restriction requirement of groups VI-LI is based upon the notice in the Official Gazette in October 1996 which states, "Applications claiming more than ten (10) individual independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement.

By statue, "[I]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the

inventions."35 U.S.C. 121. Pursuant to this statute, the rules provide that "[I]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claims shall be restricted." 37 C.F.R. 1.142(a). See also 37 C.F.R. 1.141.(a).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a **restriction requirement** pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141.

NOTE: This is a Restriction Requirement, **not** an election of species.

4. Groups I-V are independent and distinct from groups VI-LI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the kits of groups VI-LI are not disclosed as capable of use together with the methods of groups I-IV or the medicament of group V. In addition, the kits of groups VI-LI can be used in a plurality of different modes to obtain different functions and effects including use as a primer for DNA amplification, use as a probe in northern or Southern blotting, or use to identify DNA binding proteins.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
October 24, 2002

B. J. FORMAN
PATENT EXAMINER